



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,015	11/25/2003	Timothy P. Mate	341148004US2	7001

69414 7590 12/31/2008
CALYPSO MEDICAL / PERKINS COIE, LLP
P.O. BOX 1247
SEATTLE, WA 98111-1247

EXAMINER

ROZANSKI, MICHAEL T

ART UNIT	PAPER NUMBER
----------	--------------

3768

MAIL DATE	DELIVERY MODE
-----------	---------------

12/31/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/722,015	Applicant(s) MATE ET AL.	
	Examiner MICHAEL T. ROZANSKI	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 98-107 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 98-107 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/18/08 has been entered.

Claim Objections

Claims 98-107 are objected to because of the following informalities:
Amendments refer to sensors (plural), while subsequent mention of same elements is referred to as sensor (singular). Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 98-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vilsmeier et al (US 6,611,700) in view of Dumoulin et al (US 5,377,678) or Krag (US PUB 2003/0192557 with priority to 5/14/98).

Vilsmeier et al disclose a method and apparatus for positioning a patient 1 lying on a bench 9 for radiation treatment. The patient is positioned such that the isocenter 3 is located in the center of the tumor 2 to be irradiated. A glass fiber cable 6, which serves as a position sensor, is attached to a controller 8 so that the position and directional vector of the outgoing glass fiber 6 is clearly defined by a connecting point serving as a fiducial point to permit obtaining information regarding the location of the glass fiber 6 as a whole using this fiducial point. The other end of the cable 6 is implanted in the patient body 1 and fixed in the site of the tumor 2, the end point 4 of the cable 6 not being located on the tumor. By using the positional information of the cable 6 established by the controller 8, the absolute momentary position of the tumor 2 can be detected by determining the position of the end point 4 and/or of a further optional point 5 on the cable. The controller detects the three-dimensional position of individual points 4, 5 and is then able to determine whether the tumor 2 is in the permitted site circumscribing the isocenter and to suitably control the patient bench 9 to position the tumor 2 and/or the radiation source accordingly. The radiation source turns OFF when the tumor 2 moves out of the isocenter 3 and back ON when tumor 2 is in the isocenter 3 (col 4, line 56-col 5, line 26). The controller 8 is a device that loads and executes computer program code and, therefore, is a computer including computer operable instructions. In addition, the controller 8 repeatedly receives (i.e. 12 times per minute)

Art Unit: 3768

positional information of the individual points 4, 5, determines a location of the marker relative to a frame of reference defined by positional information of the glass fiber cable 6, and computes a displacement between the location of the marker and a desired location of the marker wherein the target is located at a desired situs in the reference frame when the marker is at the desired location for the marker (see col 5, lines 17-26). This also indicates that the bench 9 is moved according to the actual location of the target if a displacement between the actual location of the target and a desired location for the target is beyond an acceptable range.

Vilsmeier et al disclose that the position sensor is a glass fiber cable, thereby not transmitting information wirelessly. However, Vilsmeier et al also states that in principle, any sensor may be used as the position sensor enabling the three-dimensional location (col 2, lines 16-19). Furthermore, Vilsmeier et al teach of a unit 8 that receives the position information, rather than a plurality of sensors in a fixed and known geometry relative to each other.

Dumoulin et al or Krag teach of tracking a marker via a plurality of sensors in a fixed and known geometry relative to each other. For example, in Dumoulin et al, an RF transmit coil within the body creates an electromagnetic field which is wirelessly detected by RF receive coils 160 placed at known locations and orientations about the body. The received signals are used to determine the position and orientation of the transmit coil, or marker (col 2, line 61-col 3, line 10). The transmit coil is considered to be wireless because the signals transmitted from the transmit coil to the receive coils is done so without wire connection. Krag discloses a similar configuration in that the

Art Unit: 3768

position of an implantable marker 1100 is wirelessly sensed by a plurality of sensors 1210 in a fixed and known geometry [0150]. The marker is activated by transmitter 1220, which emits an excitation energy that causes the implantable marker to emit a response energy that is detected by sensor array 1204 (see Figures 21 and 22).

It would have been obvious to one with ordinary skill in the art at the time the invention was made to modify Vilsmeier et al, to replace the marker tracking system with one including a plurality of fixed sensors as taught by Krag or Dumoulin et al, because such is merely a substitution of one tracking system with another. Specifically, the skilled artisan would understand that the modification includes placing the marking element of Krag or Dumoulin at the site of the tumor at which the glass fiber cable 6 of Vilsmeier is fixedly attached. Such a modification would not render Vilsmeier inoperable because it involves a substitution of parts (i.e. the mechanism by which the marker at the tumor site is tracked) and does not change the principle of operation.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Art Unit: 3768

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 98-107 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-55 and 82-84 of copending Application No. 09/877,498 in view of Vilsmeier et al (US 6,611,700). '498 includes substantially all the limitations of the pending claims including the wireless implantable marker, the plurality of sensors configured to measure the marker signal, and a computer to receive the measured signals to determine the location of a selected target within a body for radiation treatment. However, '498 does not include several limitations such as the computer instructions for directing the radiation beam. Vilsmeier et al teach positioning a body on a support in view of a sensed position of a marker at the target site and providing computer instruction for directing the beam. It would have been obvious to modify '498 to include the radiation treatment features in order to facilitate radiation treatment delivery.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

Applicant's arguments with respect to claims 98-107 have been considered but are moot in view of the new ground(s) of rejection.

As an aside, it appears that the Krag reference (and other similar references to Krag) qualifies under 102(e) and has the same assignee and common inventor. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

In regard to the Dumoulin reference, the transmit coil is considered to meet the claimed limitation of the wireless marker. It is noted that it appears that the transmit coil is powered by unit 108. However, the transmit coil is still considered to be a wireless marker because the tracking signal is transmitted from transmit coil to the receive coils wirelessly. It appears Applicant could overcome this rejection by claiming that the marker is configured to be activated by induction, or an equivalent/similar limitation. However, such an amendment does not mean that the case would be in condition for

Art Unit: 3768

allowance because there are other references that may be usable to modify a Vilsmeier/Dumoulin rejection. For example, Zampini et al may be able to be used to modify Dumoulin (tracking a marker inside the body, wherein the marker is powered by a connected tracking unit 108) to teach of induction of a marker by a wireless transmitter, wherein the marker's activated signal is received by a plurality of sensors. Zampini et al is of record and was used in the rejection claims in the parent case 09/877,498, currently under Appeal.

In addition, the terminal disclaimers for 10/721,491 and 10/743,531 have been approved. However, the double patenting rejection against 09/877,498 is new.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL T. ROZANSKI whose telephone number is (571)272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3768

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768

MR